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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/378,261	08/20/1999	KENJI FUKUDOME	OMRF.152-DIV	8903

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/378,261

Applicant(s)

Fukudome et al.

Examiner

Stephen Buckler

Group Art Unit

1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/15/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☐ Claim(s) 16-17 & 24-30 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 16-17 & 21-30 is/are rejected.
- ☒ Claim(s) ~~24~~ 24-26 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. ~~Claims 16-17 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing~~
subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes methods using antibodies or parts of antibodies to bind to the receptor for endothelial cell protein C/activated protein C (APC) (see pages 21-23). In contrast, the specification is silent as to how to make oligonucleotides or receptor fragments that bind to the APC receptor as now required by the new limitation to claim 16. The disclosure only describes oligonucleotides (pages 27-31) and receptor fragments (pages 32-34) that are used in methods to downregulate the APC receptor or to bind ligand (i.e. APC), but not how to make and use oligonucleotides and receptor fragments that enhance inflammation

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by binding to the APC receptor itself, as is now required by the new claim limitation in claim 16. Because the disclosure does not describe methods using oligonucleotides and receptor fragments that bind to the APC receptor itself, as required by the new amendment to claim 16, this is a new matter rejection.

5. Claims 16-17 and ~~27~~⁷-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibody or antibody fragment immunoreactive with the receptor, does not reasonably provide enablement for any other compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification is enabling for methods using antibodies or parts of antibodies to bind to the receptor for endothelial cell protein C/activated protein C (APC) (see pages 21-23). In contrast,

the specification is silent as to how to make oligonucleotides or receptor fragments that bind to the APC receptor as now required by the new limitation to claim 16. The disclosure only describes oligonucleotides (pages 27-31) and receptor fragments (pages 32-34) that are used in methods to downregulate the APC receptor or to bind ligand (i.e. APC), but not how to make and use oligonucleotides and receptor fragments that enhance inflammation by binding to the APC receptor itself, as is now required by the new claim limitation in claim 16. The specification does not provide sufficient guidance or any working examples on how to make blocking compounds that bind to the receptor other than antibodies or antibody fragments because the blocking of receptor binding by non-antibody compounds is highly unpredictable in the protein arts because a

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compound's function cannot be adequately predicted from its amino acid sequence. The amino acid sequence of the receptor does not provide the skilled artisan with adequate guidance as to how to make ligands that can block that receptor with any reasonable expectation of success. Antibodies to the receptor that block binding are enabled because the receptor protein can simply be administered to animals in the form of a vaccine and the animal's immune system automatically makes a variety of antibodies, easily purified from serum by those of skill in the art, and some of those antibodies can be reasonably expected to interact with the receptor binding site so that they block binding. However, given just the receptor's amino acid sequence, it would require undue experimentation for the skilled artisan to make from scratch a ligand that could block receptor binding and enhance inflammation because the disclosure does not provide any working examples or sufficient guidance, such as a core chemical structure or amino acid

sequence, that possesses the biological properties required of the newly amended claim 16.

6. Claims 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. No claim is allowed.

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8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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11. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn. Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

March 18, 2002

Mary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000
